



MOREPEN LABORATORIES LIMITED

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

(The Drug & Cosmetic Act 1940 and the rules there under)

Name of Sample	FRASIX 40		
Generic Name	Frusemide Tablets IP 40 mg	A.R No.	FP3/240241
Batch No	E4C0252	Mfg. Lic No.	MNB/96/6
Batch Size	9.00 Lac	Reference No	SPC/FP/E/0129/01
Mfg. Date	Mar. 2024	Mfg. By	Morepen Laboratories Ltd.
Exp. Date	Feb. 2026	Marketed By	Healing Pharma
Sampled By	Mridul	Date of Sampling	08 th Apr. 2024
Spl. Qty.	80 Tablets	Date of Release	10 th Apr. 2024
Address	Plot no. 12 B, Sector 2, Parwanoo. (H.P.)		

S. No.	TESTS	SPECIFICATIONS/LIMITS	OBSERVATIONS
1	Description	White colored round flat faced uncoated tablets plain on both side, packed in alu-PVC blister.	White colored round flat faced uncoated tablets plain on both side, packed in alu-PVC blister.
2	Identification	(A) Maxima at about 228 nm, 271 nm and 333 nm (B) A green color produced should change to deep red.	Complies Complies
3	Average Weight	140.0 mg $\pm$ 3.0 % (135.80 mg – 144.20 mg)	139.18 mg
4	Uniformity of Weight	Average Weight $\pm$ 7.5 % (129.50 mg – 150.50 mg)	137.1 mg – 141.3 mg
5	Diameter	7.00 mm $\pm$ 0.2 mm (6.80 mm – 7.20 mm)	7.01 mm – 7.07 mm
6	Thickness	2.60 mm $\pm$ 0.2 mm (2.40 mm – 2.80 mm)	2.68 mm – 2.75 mm
7	Hardness	Not less than 2.0 kg/cm ²	3.1 kg/cm ² – 4.1 kg/cm ²
8	Friability	Not more than 1.0 % w/w	0.14 %
9	Dissolution	Not less than 70 % (Q.) of the labeled of Frusemide	Min.: 96.8 % – Max.: 99.7 %
10	Related substances		
	Any other individual impurity	Not more than 1.0 %	0.002 %
	Sum of all other impurities	Not more than 1.5 %	0.003 %
11	Assay		
	Each uncoated tablet on an average contains:		
	Frusemide IP40 mg	36.00 mg – 44.00 mg (90.0 % - 110.0 %)	39.36 mg (98.4 %)

Remarks: In the opinion of the undersigned, the sample referred to above is of Standard / not of standard quality as per IP/BP/USP In-house Specification w.r.t. above test only.

	Analysed By	Checked By	Approved By
Name	Praveen Thakur	Prabha	S.K. Yadav
Sign/Date	10/04/24	10/04/2024	10/04/24
Designation	Chemist	Sr. Chemist	Sr. Manager

GQC/011-F1-01